

## **Patient Information Leaflet**

### **PACKAGE LEAFLET: INFORMATION FOR THE USER**

#### **ROSICED 7.5 mg/g Cream**

Active substance: metronidazole

For adult use

#### **Read all of this leaflet carefully before you start using this medicine.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

#### **In this leaflet:**

1. What ROSICED 7.5mg/g Cream is and what it is used for
2. Before you use ROSICED 7.5mg/g Cream
3. How to use ROSICED 7.5mg/g Cream
4. Possible side effects
5. How to store ROSICED 7.5mg/g Cream
6. Further information

#### **1. WHAT ROSICED 7.5mg/g Cream IS AND WHAT IT IS USED FOR**

ROSICED 7.5mg/g Cream is used to treat inflammation caused by rosacea. Inflammatory rosacea is a skin condition that causes redness, papules (pink bumps) and pustules (pus-filled spots) on the face.

#### **2. BEFORE YOU USE ROSICED 7.5mg/g Cream**

##### **Do not use ROSICED 7.5mg/g Cream**

- if you are allergic (hypersensitive) to metronidazole or any of the other ingredients of ROSICED 7.5mg/g Cream . All ingredients used in ROSICED 7.5mg/g Cream are listed in section 6 of this leaflet. If you are not sure whether you are allergic, please ask your doctor or pharmacist.
- if you are in the first 3 months of pregnancy.

If you have any of the following:

- severe liver damage (e.g. cirrhosis of the liver),
- problems affecting blood formation (e.g. anaemia),

- diseases affecting the brain, bone marrow or nerves  
please tell your doctor. In such cases, treatment with ROSICED 7.5mg/g Cream must be carefully considered.

**Take special care with ROSICED 7.5mg/g Cream:**

- When using it near the eyes or mucous membranes. Such contact should be avoided. If contact occurs, the cream should be washed away carefully with water.
- If irritation does occur, ROSICED 7.5mg/g Cream should be used less frequently or should be stopped and you should seek medical advice if necessary.
- When exposing your skin to sunlight or ultraviolet (UV) light. Avoid UV exposure (sunbathing, solarium, sunlamp).
- You should not exceed the recommended duration of therapy. If required, the therapy could be repeated, however the interval of 6 weeks in between should be considered.
- ROSICED 7.5mg/g Cream should not be applied to children.
- Avoid unnecessary or prolonged use of this medication.
- If you have, or have ever had, a blood condition (dyscrasia). A dyscrasia may manifest among other symptoms as a blood clotting disorder.
- Evidence suggests that metronidazole is carcinogenic in certain animal species. There is no evidence to date of a carcinogenic effect in human.

**Using ROSICED 7.5mg/g Cream with other medicines**

*Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.*

To date, there are no known interactions with other drugs applied to the skin.

Interaction with systemic medication (oral intake, intravenous...) is unlikely because absorption of metronidazole following cutaneous application of ROSICED 7.5mg/g Cream is low.

Nevertheless, disulfiram-like reactions (reaction which may include nausea, vomiting, flushing of the skin, accelerated heart rate, and shortness of breath) occurred in small number of patients taking metronidazole and alcohol concomitantly.

Oral metronidazole has been reported to potentiate the effect of warfarin and other coumarin anticoagulants, resulting in a prolongation of prothrombin time (used to determine the clotting tendency of blood). The effect of topical metronidazole on prothrombin time is unknown.

**Pregnancy and breast-feeding**

*Ask your doctor or pharmacist for advice before taking any medicine.*

***Pregnancy***

ROSICED 7.5mg/g Cream should not be used in the first three months of pregnancy. To be on the safe side, if you are not sure whether you are pregnant, you should undergo a pregnancy test. ROSICED 7.5mg/g Cream should only be used in the last six months of pregnancy if other treatments have proved ineffective.

### ***Breast-feeding***

Metronidazole (the active substance of ROSICED 7.5mg/g Cream) passes into breast milk. During the breast-feeding period, you should either stop breast-feeding or refrain from using ROSICED 7.5mg/g Cream.

### **Children and adolescents**

There is no adequate clinical data on efficacy and safety of ROSICED 7.5mg/g Cream in children; therefore ROSICED 7.5mg/g Cream should not be applied to children

### **Driving and using machines**

ROSICED 7.5mg/g Cream has no effect on the ability to drive vehicles.

### **Important information about some of the ingredients of ROSICED 7.5mg/g Cream**

ROSICED 7.5mg/g Cream contains propylene glycol, which can cause skin irritations.

## **3. HOW TO USE ROSICED 7.5mg/g Cream**

*Always use ROSICED 7.5mg/g Cream exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.*

Always wash and dry your face gently before each application.

Non-comedogenic cosmetics (that do not clog pores and cause blackheads) and non-astringent cosmetics (that do not draw together or constrict skin and wound tissue e.g. styptic pen) may be used following application of the cream. If you are unsure, ask your doctor or pharmacist which cosmetics you can use.

### **How much and how often you should apply ROSICED 7.5mg/g Cream**

#### ***Dosage and method of administration***

Unless otherwise prescribed by your doctor, the usual dose is as follows:

Apply the cream as a **thin film twice daily** to the affected areas of the face and gently rub it in.

*Please consult your doctor or pharmacist if you have the impression that the action of ROSICED 7.5mg/g Cream is too strong or too weak.*

#### ***How long you should use ROSICED 7.5mg/g Cream***

You should normally use ROSICED 7.5mg/g Cream for a period of 6 to 12 weeks. If necessary, treatment can be continued, after an interval of 6 weeks. If no clinical improvement is achieved, treatment should be discontinued.

#### ***If you use more ROSICED 7.5mg/g Cream than you should:***

Overdosage is extremely unlikely. If necessary, the product should be removed by washing with warm water.

***If you forget to use ROSICED 7.5mg/g Cream:***

Do not take a double dose to make up for a forgotten dose. Simply carry on using ROSICED 7.5mg/g Cream at the dosage schedule prescribed by your doctor.

*If you have any further questions on the use of this product, ask your doctor or pharmacist.*

#### **4. POSSIBLE SIDE EFFECTS**

*Like all medicines, ROSICED 7.5mg/g Cream can cause side effects, although not everybody gets them.*

The evaluation of side effects is based on the following frequencies:

<b>very common:</b> more than 1 in 10 cases treated
<b>common:</b> fewer than 1 in 10, but more than 1 in 100 cases treated
<b>uncommon:</b> fewer than 1 in 100, but more than 1 in 1,000 cases treated
<b>rare:</b> fewer than 1 in 1,000, but more than 1 in 10,000 cases treated
<b>very rare:</b> fewer than 1 in 10,000 cases treated, including isolated reports

- Common side effects include Local reactions “eczema like”, worsening of rosacea, dry skin, inflammation, redness, itchiness, skin eruption, skin discomfort (burning and stinging) and pain..

-Uncommon side effects include hypothesia (reduced sense of touch or sensation) and paraesthesia (skin sensation of tingling, pricking, or numbness).

-In rare cases, swelling of the face and neck, sudden itching, fainting and breathlessness can occur. Rare side effects also include metallic taste and nausea.

*If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.*

#### **5. HOW TO STORE ROSICED 7.5mg/g Cream**

*Keep out of the reach and sight of children.*

*Do not use ROSICED 7.5mg/g Cream after the expiry date which is stated on the tube and carton after Exp. The expiry date refers to the last day of that month.*

##### **Storage conditions**

Do not store above 30°C.

Do not refrigerate or freeze.

##### **Storage once ROSICED 7.5mg/g Cream has been opened**

The cream can be used for up to 8 weeks after opening.

Do not use ROSICED 7.5mg/g Cream if you notice that the tube is damaged.

*Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.*

## **6. FURTHER INFORMATION**

### **What ROSICED 7.5mg/g Cream contains**

The active substance is: metronidazole. One gram of cream contains 7.5 mg of metronidazole.

The other ingredients are: glyceryl monolaurate, glyceryl monomyristate, propylene glycol, citric acid anhydrous, sodium hydroxide, carbomers, purified water.

### **What ROSICED 7.5mg/g Cream looks like and contents of the pack**

ROSICED 7.5mg/g Cream is available in synthetic (polyethylene) tubes containing 25 g, 30 g, 40 g and 50 g. Not all pack sizes may be marketed in all countries.

### **Marketing Authorisation Holder:**

Pierre Fabre Dermatologie  
45 place Abel Gance  
92100 Boulogne, France

### **Manufacturer**

Bioglan AB  
PO Box 50310  
S-202 13 Malmö  
Sweden

For any information on this product contact: Pierre Fabre Ltd. Phone: 01962 874400

Other formats:

To listen to or request a copy of this leaflet in Braille, large print or audio call: 0800 198 5000

Be ready to give the following information: ROSICED 7.5mg/g Cream. PL 20693/0007

This is a service provided by the Royal National Institute of the Blind.

This leaflet was last approved in: 08/2011